

**supplemental
Notice of Allowability**

Application No.

10/593,887

Examiner

SEYED AZARIAN

Applicant(s)

DEGANI ET AL.

Art Unit

2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/9/2009.
2. ☒ The allowed claim(s) is/are 1-38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
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| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>11/21/2008</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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/SEYED AZARIAN/
Primary Examiner, Art Unit 2624

Drawings

1. The drawing filed on 9/21/2006 is accepted by the Examiner.

Response to Amendment

1. Based on applicant's amendment, also telephone interview and fax inquiry filed on September 9 and 14, 2009, with respect to amended claims 1 and 19, have been fully considered and are persuasive, upon further consideration, the rejection of prior art of record for claims 1-36, are hereby withdrawn.

The claims 1-38 are allowed.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicants Attorney (Mr. Martin Fleit, Reg No. 16,900), on September 2 and 14, 2009, without traverse.

The amended claims 1 and 19 as follows:

Claim 1. (Currently Amended) A method of providing a malignancy classification for a region of lung tissue, the method comprising:

setting time points T1 and T2 measured from a time point T0 at or near an injection of a contrast agent, T1 representing a wash-in time point for malignant lung tissue at which a first concentration value of the injected contrast agent is substantially equal to or near a peak for injected contrast agent concentration for the malignant lung tissue,

wherein at T2 a second concentration value of the injected contrast agent for the malignant lung tissue is less than or substantially equal to the first concentration value at T1, and a third concentration value of the injected contrast agent for non-malignant lung tissue at T1 is less than or substantially equal to a fourth concentration value of the injected contrast agent concentration for the non-malignant lung tissue at T2;

wherein the setting of the time points T1 and T2 is determined from degree of changes in concentration values in the region of the lung tissue between time points T1 and T2 satisfying a preselected condition based on a maximum intensity predicated on microvascular permeability and extracellular volume of the region of lung tissue;

obtaining a first sample concentration value of the contrast agent for the region of lung tissue at T1 and a second sample concentration value of the contrast agent for the region of lung tissue at T2;

determining a malignancy classification for the region of lung tissue by comparing the obtained sample concentration values with a predetermined malignancy profile; and

outputting a visual representation of the malignancy classification of the region of lung tissue.

Claim 19. (Currently Amended) A computer-readable medium incorporating a program of instructions for providing a malignancy classification for a region of lung tissue, the program of

instructions comprising:

instructions for setting time points T1 and t2 measured from a time point T0 at or near an injection of a contrast agent, T1 representing a wash-in time point for malignant lung tissue at which a first concentration value of the injected contrast agent is substantially equal to or near a peak for injected contrast agent concentration for the malignant lung tissue,

wherein at T2 a second concentration value of the injected contrast agent for the malignant lung tissue is less than or substantially equal to the first concentration value at T1, and a third concentration value of the injected contrast agent for non-malignant lung tissue at T1 is less than or substantially equal to a fourth concentration value of the injected contrast agent concentration for the non-malignant lung tissue at T2;

wherein the setting of the time points T1 and T2 is determined from degree of changes in concentration values in the region of the lung tissue between time points T1 and T2 satisfying a preselected condition based on a maximum intensity predicated on microvascular permeability and extracellular volume of the region of lung tissue;

instructions for obtaining a first sample concentration value of the contrast agent for the region of lung tissue at T1 and a second concentration value of the contrast agent for the region of lung tissue at T2;

instructions for determining a malignancy classification for the region of lung tissue by comparing the obtained sample concentration values with a predetermined malignancy profile; and

instructions for outputting a visual representation of the malignancy classification of the region of lung tissue.

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance.

This invention relates generally, to medical imaging devices generally, and to methods, systems, and programs of instructions for the evaluation of potentially malignant tissue based on computed tomography (CT) or other such imaging devices.

Based on applicant's amendment, with respect to claim 1 representative of claim 19 the closest prior art of record (Klotz 7,203,353), reference directed to a method for image processing proceeding from a computer tomography (CT) image of a lung registered with a contrast agent, we well as a CT apparatus for the implementation of such a method, but does not teach or suggest, among other things, "wherein at T2 a second concentration value of the injected contrast agent for the malignant lung tissue is less than or substantially equal to the first concentration value at T1, and a third concentration value of the injected contrast agent for non-malignant lung tissue at T1 is less than or substantially equal to a fourth concentration value of the injected contrast agent concentration for the non-malignant lung tissue at T2, wherein the setting of the time points T1 and T2 is determined from degree of changes in concentration values in the region of the lung tissue between time points T1 and T2 satisfying a preselected condition based on a maximum intensity predicated on microvascular permeability and extracellular volume of the region of lung tissue; obtaining a first sample concentration value of the contrast agent for the region of lung tissue at T1 and a second sample concentration value of the contrast agent for the region of lung tissue at T2".

These key features in combination with the other features of the claimed invention are neither taught nor suggested by (Klotz) prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SEYED AZARIAN/

Primary Examiner, Art Unit 2624

February 3, 2010